Insert Molding
Solutions, Inc.

K111529

510(k) SUMMARY

Date of Preparation: 31 MAY 2011

JUL 29 2011

Company/Contact Information:
Paul Hendrixson, President
Insert Molding Solutions, Inc.
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Cumming, GA 30028
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Trade Name M-CORE disposable core biopsy needle
Common Name Biopsy Needle

Classification Name Gastroenterology-urology biopsy instrument, needle (21CFR 876.1075, Product Code KNW)

Name of Predicate(s) or Legally Marketed Device(s)
K092059 – Riverpoint Medical RP Cutting Needle
K883469 –C.R. Bard® Aspiration Biopsy System ("Magnum®")
K994272- Promex MCN Automated Core Biopsy Device

Device Description
The M-CORE disposable core biopsy needle is a sterile, disposable biopsy needle featuring stainless steel cutting cannula and stylet, with sample notch. The cannula and stylet each have a molded thermoplastic hub. A thermoplastic removable spacer is provided to allow easy insertion of both hubs into a Bard® Magnum® reusable biopsy instrument. An LDPE sheath is provided to protect the needle and packaging from damage. The needles are available in gauges from 14 – 18 and lengths from 10 – 25 centimeters.

Indications for Use
The M-CORE disposable biopsy needle is intended for use with the Bard® Magnum® biopsy instrument in obtaining biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. The M-CORE needle is not intended for use in bone.

Substantial Equivalence
The M-CORE disposable biopsy needle has the same intended use as the predicate device(s) and has the same technological characteristics in terms of basic design and materials.

Characteristic	RP Cutting Needle	Magnum Needle	MCN Needle	M-CORE Needle
Manufacturer	Riverpoint Medical	C.R. Bard	Promex	Insert Molding Solutions
510(k) Number	K092059	K883469	K994272	
Cannula and Stylet Material	304SS	304SS	304SS	304SS
Cannula and Stylet Hub Material	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Sheath	LDPE	LDPE	LDPE	LDPE
Stylet Sample Notch	19mm	19mm	19mm	19mm
Spacer	Thermoplastic	Thermoplastic	Thermoplastic	Thermoplastic
Non-Pyrogenic	Yes	Yes	Yes	Yes, LAL Test
Sterile Packaging	Tyvek pouch	Tyvek pouch	Tyvek pouch	Tyvek pouch
Sterilization Method	EO, SAL 10^{-6}	EO, SAL 10^{-6}	Gamma, 11137, VDMax^{25}, SAL 10^{-6} Dose: 25 – 40 kGy,	Gamma, 11137, VDMax^{25}, SAL 10^{-6} Dose: 25 – 40 kGy,

Performance Testing Summary
Performance testing confirms that the quality of the samples obtained with the M-CORE disposable core biopsy needle is substantially equivalent to that of the predicate device(s). See Section 18 for Performance Testing details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Paul Hendrixson
President
Insert Molding Solutions, Inc.
4325 Settingdown Circle, Suite 103
CUMMING GA 30028

JUL 29 2011

Re: K111529
Trade/Device Name: M-CORE disposable core biopsy needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: June 27, 2011
Received: June 29, 2011

Dear Mr. Hendrixson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Insert Molding
Solutions, Inc.

Indications for Use

510(k) Number (if known): K111529

Device Name: M-CORE disposable core biopsy needle

Indications For Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111529

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